



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Aladar Szalay et al.
Serial No. : 10/849,664
Filed : May 19, 2004

Art Unit : 1632
Examiner : Robert M. Kelly
Cust. No. : 20985
Conf. No. : 7765

Title : LIGHT EMITTING MICROORGANISMS AND CELLS FOR DIAGNOSIS
AND THERAPY OF DISEASES ASSOCIATED WITH WOUNDED OR
INFLAMED TISSUE

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

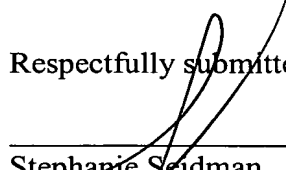
Dear Sir:

Transmitted herewith are a Supplemental Information Disclosure Statement, Form PTO-1449 (6 pages), copy of Foreign Office Action, cited non U.S. patent references, and a return postcard for filing in connection with the above-identified application. Because this Supplemental Information Disclosure Statement is filed prior to receipt of a first Office Action on the merits for the above-captioned application, a fee for filing this statement should not be due. However, should it be determined that a fee for filing these papers is required, the Commissioner is authorized to charge Deposit Account No, 06-1050, as stated below:



The Commissioner is hereby authorized to charge the fee for the extension of time and any other fee that may be due in connection with this and the attached papers or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,


Stephanie Seidman
Reg. No. 33,779

Dated: April 5, 2006
Attorney's Docket No.: 17248-004002 / 4804B
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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN
ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98**

Because this Supplemental Information Disclosure Statement is filed before the receipt of a First Office Action on the Merits for the above-captioned application, a fee for filing this statement should not be due. If, however, it is determined that a fee is due, any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Forms PTO-1449 (6 pages) and copies of the cited non U.S. Patent documents are provided herewith in connection with the above-captioned application.

The documents cited on the Forms PTO-1449 are in the English language, with the exception of items noted below. Item BA (JP2002097144) is in the Japanese language and is provided with an English equivalent (Item AA, US 2002/054865); Item BB (JP55035004) is in the Japanese language and is provided with a Derwent Abstract (Item CC); Item CY (Muravlev *et al.*) is in the Russian language and includes an English language summary on the last page of the article; Item CZ (Netesova *et al.*) is in the Russian language and includes an English language summary on the last page of the article; Item DC (Pak *et al.*) is in the Russian language and includes an English language summary on the last page of the article; Item DI (Prikhod'ko *et al.*, pp. 955-963) is in the Russian language and includes an English language summary on the last page of the article; Item DJ (Prikhod'ko *et al.*, pp. 13-26) is in the Russian language and includes and English language summary on the last page of the article; and Item DW (Vogt *et al.*) is in the German language and includes an English

language summary on the last page of the article. Further, Item BY is the certified English translation of the abstract of Aksac *et al.*, which was previously submitted as Item Q in the Supplemental Information Disclosure Statement mailed on August 03, 2005; and Item BZ is the certified English translation of Al'tshtein *et al.*, which was previously submitted as Item R in the Supplemental Information Disclosure Statement mailed on August 03, 2005. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

The Applicant makes known to the Examiner Foreign Office Actions received for the corresponding Foreign applications. Provided herewith is a copy of a Foreign Office Action, issued March 10, 2006, in connection with corresponding European Patent Application No. 03735553.4.

Applicant also makes known to the Patent and Trademark Office the grant of a Retroactive Foreign Filing License on March, 28, 2006 for the subject matter in U.S. patent application No. 10/163,763 (attorney docket No: 17248-004001/4804, now abandoned) which is the parent application of the instant continuation application No. 10/849,664 (attorney docket No. 17248-004002/ 4804B).

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g and h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant : Szalay et al.
Serial No. : 10/849,664
Filed : May 19, 2004

Attorney's Docket No: 17248-004002 / 4804B
Supplemental Information Disclosure Statement

Applicant respectfully requests that the Examiner review the foregoing references and they be made of record in the file history of the above-captioned application.

Respectfully submitted,

Stephanie Seidman
Reg. No. 33,779

Dated: April 5, 2006

Attorney's Docket No: 17248-004002 / 4804B

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Sheet 1 of 6

Substitute Form PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office		Attorney's Docket No. 17248-004002/4804B	Application No. 10/849,664		
List of Patents and Publications for Applicant's Information Disclosure Statement (37 CFR §1.98(b))				Applicant Aladar A. Szalay et al.			
				Filing Date May 19, 2004		Group Art Unit 1632	

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	2002/0054865	05/09/02	Fujimori et al.	424	93.21	03/26/01
	AB	2003/0031628	02/13/03	Zhao et al.	424	9.6	07/09/02
	AC	2003/0044384	03/06/03	Roberts et al.	424	93.2	01/15/02
	AD	2003/0161788	08/28/03	Zhao et al.	424	9.6	12/31/02
	AE	2003/0165477	09/04/03	Balloul et al.	424	93.21	04/12/01
	AF	2004/0076622	04/22/04	Studený et al.	424	93.21	02/28/03
	AG	2005/0249670	11/10/95	Szalay et al.	424	9.32	06/27/05
	AH	2006/0051370	03/09/06	Szalay et al.	424	199.1	09/27/05
	AI	5,650,135	07/22/97	Contag et al.	424	9.1	07/01/94
	AJ	6,007,806	12/28/99	Lathe et al.	424	93.2	12/12/97
	AK	6,099,848	08/08/00	Frankel et al.	424	246.1	11/18/97
	AL	6,232,523	05/15/01	Tan et al.	800	10	04/28/97
	AM	6,235,967	05/22/01	Tan et al.	800	10	03/27/98
	AN	6,235,968	05/22/01	Tan et al.	800	10	04/28/98
	AO	6,251,384	06/26/01	Tan et al.	424	93.21	01/07/99
	AP	6,416,754	07/09/02	Brown et al.	424	93.21	07/23/96
	AQ	6,589,531	07/08/03	Andino-Pavlovsky et al.	424	199.1	09/01/00
	AR	6,627,190	09/30/03	Wold et al.	424	93.2	09/19/01
	AS	6,649,143	11/18/03	Contag et al.	424	9.1	01/19/99
	AT	6,649,159	11/18/03	Yang et al.	424	93.21	03/19/01
	AU	6,652,849	11/25/00	Brown et al.	424	93.2	05/17/02
	AV	6,759,038	06/06/04	Tan et al.	424	93.21	05/29/01
	AW	6,984,374	01/10/06	Szalay et al.	123	435	01/30/03

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
	AX	0 861 093	09/28/98	EP			Yes	No
	AY	1 146 125	10/17/01	EP				
	AZ	1 254 250	03/23/05	EP				

Examiner Signature	Date Considered
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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				Filing Date May 19, 2004		Group Art Unit 1632		
Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	BA	2002097144	04/02/02	JP				X+
	BB	55035004	03/11/80	JP				X*
	BC	01/12234	02/22/01	PCT				
	BD	01/20989 /	03/29/01	PCT				
	BE	01/55444	08/02/01	PCT				
	BF	03/006069	01/23/03	PCT				
	BG	03/057007	07/17/03	PCT				
	BH	03/092600	11/13/03	PCT				
	BI	03/102169	12/11/03	PCT				
	BJ	2004/044175 /	05/27/04	PCT				
	BK	2005/047458	05/26/05	PCT				
	BL	2005/057488	06/23/05	PCT				
	BM	2005/072622	08/11/05	PCT				
	BN	97/18841	05/29/97	PCT				

X+ = An English language equivalent is provided

X* = An English language Derwent abstract is provided

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	BO	"WHO Collaborating Centre for Orthopoxvirus Diagnosis and Repository for Variola Virus Strains and DNA," VECTOR: Ministry of Public Health and Social Development of Russian Federation, State Research Center of Virology and Biotechnology http://www.vector.nsc.ru/DesktopDefault.aspx?lcid=9&tabid=294&tabindex=1 (accessed on 09/12/05)
	BP	"A New Way to Kill Cancer: SLU Research Shows Viruses can destroy lung, colon tumors," Science Daily: Your link to the latest research news http://www.sciencedaily.com/releases/2004/05/040517071951.htm (accessed on 05/17/04)
	BQ	Advani et al., "Replication-competent, Nonneuroinvasive Genetically Engineered Herpes Virus Is Highly Effective in the Treatment of Therapy-resistant Experimental Human Tumors," Cancer Research 59: 2055-2058 (1999)
	BR	Altenbrunn et al., "Scintigraphic Tumor Localization in Mice with Radioiodinated Anti- <i>Clostridium</i> Antibodies," Int. J. Nucl. Med. Biol. 8(1): 90-93 (1981)
	BS	Bennett et al., "Positron emission tomography imaging for herpes virus infection: Implications for oncolytic viral treatments of cancer," Nature Med 7(7): 859-863 (2001)

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Substitute Form PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 17248-004002/4804B	Application No. 10/849,664
List of Patents and Publications for Applicant's Information Disclosure Statement (37 CFR §1.98(b))			Applicant Aladar A. Szalay et al.	
			Filing Date May 19, 2004	Group Art Unit 1632
Other Documents (include Author, Title, Date, and Place of Publication)				
Examiner Initial	Desig. ID	Document		
	BT	Berger, F. and S.S. Gambhir, "Recent advances in imaging endogenous or transferred gene expression utilizing radionuclide technologies in living subjects," Breast Cancer Research 3: 28-35 (2001)		
	BU	Blasberg, R.G. and J.G. Tjuvajev, "Herpes simplex virus thymidine kinase as a marker/reporter gene for PET imaging of gene therapy," Q J Nucl Med 43(2): 163-169 (1999)		
	BV	Boland et al., "Adenovirus-mediated Transfer of the Thyroid Sodium/Iodide Symporter Gene into Tumors for a Targeted Radiotherapy," Cancer Research 60: 3484-3492 (2000)		
	BW	Bonnekoh et al., "Adenoviral-Mediated Herpes Simplex Virus-Thymidine Kinase Gene Transfer <i>in Vivo</i> for Treatment of Experimental Human Melanoma," J. Invest. Dermatol. 106(6): 1163-1168 (1996)		
	BX	Brockstedt et al., "Development of Anti-tumor Immunity against a Non-immunogenic Mammary Carcinoma through <i>in Vivo</i> Somatic GM-CSF, IL-2, and HSVtk Combination Gene Therapy," Mol. Ther. 6(5): 627-636 (2002)		
	BY	Certified English translation of abstract for Aksac S., "[Antibody formation against Agrobacterium tumefaciens in patients with various cancers]," Turk Hij Tecz Biyol Derg. 34(1-2):48-51 (1974) [Article in Italian].		
	BZ	Certified English translation of journal article for Al'tshtein [Altshteyn] et al., "[Isolation of a recombinant vaccinia virus based on the LIVP strain inducing the surface antigen of the hepatitis B virus]," Dokl Akad Nauk SSSR. 285(3):696-9 (1985) [Article in Russian].		
	CA	Chen B et al., "Evaluation of Cytokine Toxicity Induced by Vaccinia Virus-mediated IL-2 and IL-2 Antitumor Immunotherapy," Cytokine (2001) 15(61):305-314.		
	CB	Chaudhuri et al., "Light-based imaging of green fluorescent protein-positive ovarian cancer xenografts during therapy," Gynecol. Oncol. 82(3): 581-589 (2001)		
	CC	Derwent English abstract for Japanese Patent Publication JP 55035004, published February 3, 1987, entitled, "Cellular immuno-potentiator - contg. Vaccinia attenuated virus showing no infectivity to man or rabbit and has lost humoral immunity," Derwent Accession Number: 2512008		
	CD	Fabricius et al., "Quantitative investigations into the elimination of <i>in vitro</i> -obtained spores of the non-pathogenic <i>Clostridium butyricum</i> strain CNRZ 528, and their persistence in organs of different species following intravenous spore administration," Res. Microbiol. 144: 741-753 (1993)		
	CE	Francis et al., "Monitoring bioluminescent <i>staphylococcus aureus</i> infections in living mice using a novel <i>lux</i> ABCDE construct," Infection and Immunity 68(6): 3594-3600 (2000)		
	CF	Gambhir et al., "Imaging transgene expression with radionuclide imaging technologies," Neoplasia 2(1-2): 118-138 (2000)		
	CG	Gnant et al., "Regional <i>Versus</i> Systemic Delivery of Recombinant Vaccinia Virus as Suicide Gene Therapy for Murine Liver Metastases," Annals of Surgery 230(3): 352-361 (1999)		
	CH	Gnant et al., "Sensitization of tumor necrosis factor α -resistant human melanoma by tumor-specific <i>in vivo</i> transfer of the gene encoding endothelial monocyte-activating polypeptide II using recombinant vaccinia virus," Cancer Research 59: 4668-4674 (1999)		
	CI	Hamblin et al., "Rapid control of wound infections by targeted photodynamic therapy monitored by <i>in vivo</i> bioluminescence imaging," Photochemistry and Photobiology 75(1): 51-57 (2002)		
	CJ	Hansen et al., "Assessment of GFP fluorescence in cells of <i>Streptococcus gordonii</i> under conditions of low pH and low oxygen concentration," Microbiology 147: 1383-1391 (2001)		
	CK	Hasegawa et al., " <i>In vivo</i> tumor delivery of the green fluorescent protein gene to report future occurrence of metastasis," Cancer Gene Therapy 7: 1336-1340 (2000)		

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				Filing Date May 19, 2004	Group Art Unit 1632
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Examiner Initial	Desig. ID	Document			
	CL	Hatta, M., "Antitumor mechanisms of <i>Eubacterium lentum</i> and its components," Asian Pacific Journal of Allergy and Immunology 13: 129-137 (1995)			
	CM	Hiller et al., "Characterization of Intracellular and Extracellular Vaccinia Virus Variants: N ₁ -Isonicotinoyl-N ₂ -3-Methyl-4-Chlorobenzoylhydrazine Interferes with Cytoplasmic Virus Dissemination and Release," Journal of Virology 39(3): 903-913 (1981)			
	CN	Ianaro et al., "Expression of TGF- β in attenuated <i>Salmonella typhimurium</i> : oral administration leads to the reduction of inflammation, IL-2 and IFN- γ , but enhancement of IL-10, in carrageenin-induced oedema in mice," Immunology 84:8-15 (1995)			
	CO	Jacobs et al., "Positron Emission Tomography-based Imaging of Transgene Expression Mediated by Replication-conditional, Oncolytic Herpes Simplex Virus Type I Mutant Vectors <i>in Vivo</i> ," Cancer Research 61: 2983-2995 (2001)			
	CP	Jain, R.K. and N.S. Forbes, "Can engineered bacteria help control cancer," Proc. Natl. Acad. Sci. USA 98(26): 14748-14750 (2001)			
	CQ	Joklik, W.K., "The Purification of Four Strains of Poxviruses," Virology 18:9-18 (1962)			
	CR	Kaplitt et al., "Mutant herpes simplex virus induced regression of tumors growing in immunocompetent rats," J. Neurooncol 19(2): 137-147 (1994)			
	CS	Kim, D.H. and F. McCormick, "Replicating viruses as selective cancer therapeutics," Mol Med Today 2(12): 519-527 (1996)			
	CT	Kutinova et al., "Search for optimal parent for recombinant vaccinia virus vaccines. Study of three vaccinia virus vaccinal strains and several virus lines derived from them," Vaccine 13(5): 487-493 (1995)			
	CU	Lattime et al., "In Situ Cytokine Gene Transfection Using Vaccinia Virus Vectors," Semin Oncol 23(1): 88-100 (1996)			
	CV	Mackenzie et al., "Human mesenchymal stem cells persist, demonstrate site-specific multipotential differentiation, and are present in sites of wound healing and tissue regeneration after transplantation into fetal sheep," Blood Cells, Molecules, and Diseases 27(3): 601-604 (2001)			
	CW	Meyer et al., "Mapping of deletions in the genome of the highly attenuated vaccinia virus MVA and their influence on virulence," Journal of General Virology 72(Pt 5): 1031-1038 (1991)			
	CX	Morinaga et al., "Antitumor activity and its properties of <i>Eubacterium lentum</i> ," Jpn. J. Cancer Res. (Gann) 79: 117-124 (1988)			
	CY	Muravlev et al., "Protective activity of vaccinia virus envelope proteins isolated with the use of nonionic detergents," Voprosy Virusologii 40(4): 154-8 (1995) [article in Russian, English summary on last page of article]			
	CZ	Netesova et al., "Structural and functional studies of the <i>HindIII</i> -I-Genome Fragment of Vaccinia virus Strain L-IVP," Mol Biol (Mosk.) Nov-Dec; 25(6): 1526-32 (1991) [article in Russian, English summary on last page of article]			
	DA	Norton et al., "Expression of Secreted Platelet-Derived Growth Factor-B by Recombinant Nonreplicating and Noncytopathic Vaccinia Virus," Annals of Surgery 224(4):555-562 (1996)			
	DB	Overwijk et al., "Vaccination with a recombinant vaccinia virus encoding a 'self' antigen induces autoimmune vitiligo and tumor cell destruction in mice: Requirement for CD4 ⁺ T lymphocytes," Proc. Natl. Acad. Sci. USA 96: 2982-2987 (1999)			
	DC	Pak et al., "Cloning of the growth factor gene from vaccinia virus L1VP strain in <i>Escherichia coli</i> cells," Mol Gen Mikrobiol Virusol Sept-Oct; (9-10):19-21 (1992) [article in Russian, English summary on last page of article]			
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	DD	Pan et al., "Regression of Established B16F10 Melanoma with a Recombinant <i>Listeria monocytogenes</i> Vaccine," Cancer Research 59:5264-5269 (1999)		
	DE	Peplinski et al., "In vivo gene therapy of a murine pancreas tumor with recombinant vaccinia virus encoding human interleukin-1beta," Surgery 118:185-191 (1995)		
	DF	Phillips-Jones, M.K., "Bioluminescence (<i>lux</i>) expression in the anaerobe <i>Clostridium perfringens</i> ," FEMS Microbiology Letters 106: 265-270 (1993)		
	DG	Phillips-Jones, M.K., "Use of <i>lux</i> reporter system for monitoring rapid changes in α -toxin gene expression in <i>Clostridium perfringens</i> during growth," FEMS Microbiology Letters 188: 29-33 (2000)		
	DH	Poptani et al., "Monitoring thymidine kinase and ganciclovir-induced changes in rat malignant glioma <i>in vivo</i> by nuclear magnetic resonance imaging," Cancer Gene Ther 5(2): 101-109 (1998)		
	DI	Prikhod'ko, G. G. et al., "Cloning, Sequencing and Translation Analysis of the Vaccinia Virus L1VP HindIII N Fragment," Genetika 27(6): 955-963 (1991)) [article in Russian, English summary on last page of article]		
	DJ	Prikhod'ko, G. G. and IV Babkin, "5'-variable genome sequence of vaccinia virus L1VP. Possible role of short direct repeats in formation of DNA deletions," Genetika 27(1): 13-26 (1991) [article in Russian, English summary on last page of article]		
	DK	Qazi et al., "Real-time monitoring of intracellular <i>Staphylococcus aureus</i> replication," J Bacteriol. 186(4): 1065-1077 (2004)		
	DL	Rocchetta et al., "Validation of a Noninvasive, Real-Time Imaging Technology Using Bioluminescent <i>Escherichia coli</i> in the Neutropenic Mouse Thigh Model of Infection," Antimicrobial Agents and Chemotherapy 45(1): 129-137 (2001)		
	DM	Sakamoto et al., "Antitumor effect of normal intestinal microflora on Ehrlich Ascites tumor," Jpn. J. Cancer Res. (Gann) 79: 109-116 (1988)		
	DN	Scholl et al., "Recombinant Vaccinia Virus Encoding Human <i>MUC1</i> and <i>IL2</i> as Immunotherapy in Patients with Breast Cancer," J. Immunother 23(5): 570-580 (2000)		
	DO	Shchelkunov et al., "The gene encoding the late nonstructural 36K protein of vaccinia virus is essential for virus reproduction," Virus Research 28: 273-283 (1993)		
	DP	Shimizu et al., "Antitumor activity of marine bacteria, <i>vibrio anguillarum</i> , in mice," Gann 70: 429-433 (1979)		
	DQ	Shimizu et al., "Antitumor activity of 2-keto-3-deoxyoctonate-free lipopolysaccharide of <i>vibrio anguillarum</i> in mice," Gann 74(2): 279-284 (1983)		
	DR	Studený et al., "Bone Marrow-derived Mesenchymal Stem Cells as Vehicles for Interferon- β Delivery into Tumors," Cancer Research 62: 3603-3608 (2002)		
	DS	Tjuvajev et al., "Noninvasive Imaging of Herpes Virus Thymidine Kinase Gene Therapy and Expression: A Potential Method for Monitoring Clinical Gene Therapy," Cancer Res 56(18): 4087-4095 (1996)		
	DT	Tjuvajev et al., "Imaging the Expression of Transfected Genes <i>in Vivo</i> ," Cancer Res. 55(24): 6126-6132 (1995)		
	DU	Tjuvajev et al., "Imaging Adenoviral-mediated Herpes Virus Thymidine Kinase Gene Transfer and Expression <i>In Vivo</i> ," Cancer Research 59: 5186-5193 (1999)		
	DV	Tjuvajev et al., "Imaging Herpes Virus Thymidine Kinase Gene Transfer and Expression by Positron Emission Tomography," Cancer Res. 58(19): 4333-4341 (1998)		

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	DW	Vogt et al., "Untersuchungen über die Möglichkeit der Tumorlokalisation in vivo auf ser Basis eines szintigrafischer Klostridienstäbchen-Nachweises mit ¹³¹ J-markierten Antikörpern und F(ab') ₂ -Antikörperfragmenten," Zeitschrift für Experimentelle Chirurgie 12(4): 209-215 (1979) [article in German, English summary on the last page of the article]			
	DX	Volm et al., "Enhancement of Incorporation of ¹³¹ Iododeoxyuridine into Tumors after Application of <i>Clostridium oncolyticum</i> s. <i>butyricum</i> (M 55)," Eur. J. Nucl. Med. 2(2): 117-120 (1977)			
	DY	Xie et al., "Adenovirus-mediated Tissue-targeted Expression of a Caspase-9-based Artificial Death Switch for the Treatment of Prostate Cancer," Cancer Research 61: 6795-6804 (2001)			
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	EA	Zhao et al., "Spatial-temporal imaging of bacterial infection and antibiotic response in intact animals," Proceeding of the National Academy of Sciences 98(17): 9814-9818 (2001)			
	EB	Zinoviev et al., "Identification of the gene encoding vaccinia virus immunodominant protein p35," Gene 147: 209-214 (1994)			

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